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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,468	10/22/2003	Stephen C. Strom	12958/46103	5954

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,468	STROM ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-39 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction

I. Claims 1-4, drawn to a composition or a pharmaceutical composition comprising a placental stem cell of the present invention, classified in class 435, subclass 372.

II. Claim 5, drawn to a method of making a cardiomyocyte using the placental stem cell of the present invention, classified in class 435, subclass 377.

III. Claims 6-9, drawn to a composition or a pharmaceutical composition comprising a cardiomyocyte, classified in class 435, subclass 372.

IV. Claims 10-11, drawn to a method of determining whether a test agent is toxic to a cardiomyocyte or for determining a metabolic product of a test agent using a cardiomyocyte, classified in class 435, subclass 375.

V. Claims 12, drawn to a method of making a hepatocyte comprising culturing the placental stem cell of the present invention, classified in class 435, subclass 377.

VI. Claims 13-16, drawn to a composition or a pharmaceutical composition comprising a hepatocyte, classified in class 435, subclass 370.

VII. Claims 17-18, drawn to a method of determining whether a test agent is toxic to a hepatocyte or for determining a metabolic product of a test agent using a hepatocyte, classified in class 435, subclass 375.

VIII. Claim 19, drawn to a method of making a pancreatic cell comprising culturing the placental stem cell of the present invention, classified in class 435, subclass 377.

IX. Claims 20-23, drawn to a composition or a pharmaceutical composition comprising a pancreatic cell, classified in class 435, subclass 370.

X. Claims 24-25, drawn to a method of determining whether a test agent is toxic to a pancreatic cell or for determining a metabolic product of a test agent using a pancreatic cell, classified in class 435, subclass 375.

XI. Claim 26, drawn to a method of making a neural cell comprising culturing the placental stem cell of the present invention, classified in class 435, subclass 377.

XII. Claims 27-30, drawn to a composition or a pharmaceutical composition comprising a neural cell, classified in class 435, subclass 368.

XIII. Claims 31-32, drawn to a method of determining whether a test agent is toxic to a neural cell or for determining a metabolic product of a test agent using a neural cell, classified in class 435, subclass 375.

XIV. Claim 33, drawn to a method of making a vascular endothelial cell comprising culturing the placental stem cell of the present invention, classified in class 435, subclass 377.

XV. Claims 34-37, drawn to a composition or a pharmaceutical composition comprising a vascular endothelial cell, classified in class 435, subclass 372.

XVI. Claims 38-39, drawn to a method of determining whether a test agent is toxic to a vascular endothelial cell or for determining a metabolic product of a test agent using a vascular endothelial cell, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

The compositions of Groups I, III, VI, IX, XII and XV are distinct biochemically and physically one from the others. For example, the placental stem cell of Group I is distinct from a cardiomyocyte of Group III, a hepatocyte of Group VI, a pancreatic cell of Group IX, a neural cell of Group XII, and a a vascular endothelial cell of Group XV.

The methods of Groups II, IV-V, VII-VIII, X-XI, XIII-XIV and XVI are independent and distinct one from the others because they contain different method steps, different starting materials and different desired outcomes that require different technical considerations for achieving the end-results. For example, the methods of Groups II, V, VIII, XI and XIV are drawn to methods of making a cardiomyocyte, hepatocyte, pancreatic cell, neural cell and vascular endothelial cell, respectively; whereas the methods of Groups IV, VII, X, XIII and XVI are directed to screening methods for

determining a toxic agent to a cardiomyocyte or for determining a metabolic product of a test agent using a cardiomyocyte, hepatocyte, pancreatic cell, neural cell and vascular endothelial cell, respectively.

Inventions I and Inventions II, V, VIII, XI, XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the placental stem cell of Group I can be used in any of the distinct methods of Groups II, V, VIII, XI and XIV.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, a cardiomyocyte can be made at least from an isolated ES cell.

Inventions II and IV are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, a hepatocyte can be made at least from an isolated ES cell.

Inventions V and VII are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions VIII and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, a pancreatic cell can be made at least from an isolated ES cell.

Inventions VIII and X are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions XI and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, a neural cell can be made at least from an isolated ES cell.

Inventions XI and XIII are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions XIV and XV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, a vascular endothelial cell can be made at least from an isolated ES cell.

Inventions XIV and XVI are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Other combinations of the aforementioned Inventions are not related.

Searching and examining the inventions of Groups I-XVII would impose a serious burden due to the distinctness of each Invention as discussed in detail above. It would be unduly burdensome for the examiner to perform a complete search of the defined areas in both **the patent and non-paten literature**, and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction

A. Should Applicants elect the invention of Group I, this application contains claims directed to the following patentably distinct species of the claimed invention:

A specifically named marker or a specific combination of markers as listed in the Markush group of claim 1 or 2.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4 are generic.

B. Should Applicants elect the invention of either Group III or IV, this application contains claims directed to the following patentably distinct species of the claimed invention:

A specifically named marker or a specific combination of markers as listed in the Markush group of claim 6 or 7.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6-11 are generic.

C. Should Applicants elect the invention of either Group VI or VII, this application contains claims directed to the following patentably distinct species of the claimed invention:

A specifically named marker or a specific combination of markers as listed in the Markush group of claim 13 or 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 13-18 are generic.

D. Should Applicants elect the invention of either Group IX or X, this application contains claims directed to the following patentably distinct species of the claimed invention:

A specifically named marker or a specific combination of markers as listed in the Markush group of claim 20 or 21.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 20-25 are generic.

E. Should Applicants elect the invention of either Group XII or XIII, this application contains claims directed to the following patentably distinct species of the claimed invention:

A specifically named marker or a specific combination of markers as listed in the Markush group of claim 27 or 28.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27-32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Dave Nguyen, at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

QUANG NGUYEN, PH.D
PATENT EXAMINER